### **HEALTH**

# Cooperation

Agreement Between the UNITED STATES OF AMERICA and INDIA

Signed at Geneva May 20, 2008



#### NOTE BY THE DEPARTMENT OF STATE

Pursuant to Public Law 89—497, approved July 8, 1966 (80 Stat. 271; 1 U.S.C. 113)—

"...the Treaties and Other International Acts Series issued under the authority of the Secretary of State shall be competent evidence... of the treaties, international agreements other than treaties, and proclamations by the President of such treaties and international agreements other than treaties, as the case may be, therein contained, in all the courts of law and equity and of maritime jurisdiction, and in all the tribunals and public offices of the United States, and of the several States, without any further proof or authentication thereof."

## **INDIA**

Health: Cooperation

Agreement signed at Geneva May 20, 2008; Entered into force May 20, 2008.

#### AGREEMENT BETWEEN THE

# NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE

INDIAN COUNCIL OF MEDICAL RESEARCH,
DEPARTMENT OF HEALTH RESEARCH,
MINISTRY OF HEALTH AND FAMILY WELFARE
FOR

# COOPERATION ON AN INTERNATIONAL CENTER OF EXCELLENCE IN RESEARCH IN CHENNAL, INDIA

The National Institute of Allergy and Infectious Diseases ("NIAID"), part of the National Institutes of Health ("NIH"), an agency of the U.S. Department of Health and Human Services ("HHS"), and the Indian Council of Medical Research ("ICMR") of the Department of Health Research of the Ministry of Health and Family Welfare, hereinafter referred to as the "Parties":

Recognizing that the Government of the United States of America and the Government of the Republic of India concluded an Agreement on Science and Technology Cooperation on October 17, 2005 (hereinafter referred to as the "S&T Agreement");

Acknowledging that HHS/NIH/NIAID and ICMR signed a Joint Statement for the Establishment of an International Center for Excellence in Research (ICER) at the Tuberculosis Research Centre in Chennai in June 2003; and

Seeking to build upon the success of the ICER program, and supersede the 2003 Joint Statement for the Establishment of an ICER;

Have agreed as follows:

#### Article 1. Scientific Focus

- 1. The Parties agree to continue ongoing activities, and to identify areas of mutual interest for expanded cooperation in scientific areas, including but not limited to epidemiology, medicine, molecular biology, medical entomology, parasitology, immunology, bacteriology, microbiology and virology, with a focus on techniques for the prevention, diagnosis and treatment of tropical infectious and allergic diseases.
- 2. The focus of collaboration may include, but is not limited to, the following diseases:
  - Tuberculosis
  - Parasitic Infections
  - HIV/AIDS
  - Allergic Diseases

- Immune System Diseases
- Other Emerging and Re-Emerging Pathogens
- Other diseases of shared scientific interest

#### Article 2. Mechanisms of Cooperation

The cooperation undertaken pursuant to this Agreement may include, but is not limited to:

- Collaborative research projects;
- Exchange of scientists and researchers:
- Scientific meetings, workshops and symposia;
- Training activities and consultations;
- Long-term assignment of scientists and researchers to undertake joint research;
- Enhancement and strengthening of biomedical/infectious disease research capacity, including clinical research infrastructure, data and information management systems, and sample repositories;
- Exchange of research materials, data, technology and scientific publications;
- Other forms of cooperation identified by mutual consent.

#### Article 3. Facilities and Management

- 1. The Parties' cooperation under this Agreement will be undertaken primarily in Chennai, India, within the Tuberculosis Research Centre (TRC) of the Indian Council of Medical Research (ICMR).
- 2. As its contribution to the development and support of the ICER, the ICMR will provide:
  - Access to TRC laboratory facilities for joint collaborative projects, particularly those facilities strengthened under the ICER program;
  - General maintenance of the facilities housing the ICER laboratories, including utilities, waste disposal and general upkeep;
  - Continued adherence to international biosafety standards for ICER laboratory facilities and equipment;
  - Appropriately qualified research and support staff, as determined by the Parties, to perform collaborative projects and support functions;
  - Laboratory and technical support for scientists on long-term assignments in ICER laboratories, as defined under the Exchange of Personnel section;
  - Administrative support to facilitate research activities and to expedite all required clearances for U.S. and Indian scientists working under this program.
- 3. As its contribution to the development and support of the ICER, HHS/NIH/NIAID will provide, subject to the availability of funds and personnel:
  - Scientific engagement with ICER associated research facilities and laboratories;

- Support to enhance laboratory capacity at the TRC, as determined through mutual discussion and research program needs;
- Ongoing maintenance of ICER laboratories and associated equipment;
- Scientists for long-term research collaboration and joint scientific protocol implementation, as defined under the Exchange of Personnel section;
- Assistance, with research tools and capabilities required for research projects;
- Training and exchange opportunities in NIH laboratories.
- 4. Each Party is expected to designate a project implementation coordinator to plan, approve, and monitor activities under this Agreement. The coordinators, and/or their designees, shall communicate regularly and meet periodically, as necessary, to evaluate the activities carried out under this joint program, to resolve issues, and to ensure the efficient completion of collaborative research.

#### Article 4. Additional Participating Organizations

In addition to the Parties, other participants may join in cooperative activities under this Agreement. These participants may include individuals and institutions in the public, private, and academic sectors; State and local Governments of both countries; and other entities, as identified by the Parties. Additionally, the Parties may invite scientists, technical experts, and other entities of third countries, international organizations, and non-governmental organizations to participate, as appropriate, in projects and programs, with the mutual consent of the Parties or their implementing entities.

#### Article 5. Exchange of Personnel

Unless otherwise agreed in writing, the following provisions shall govern the assignment or exchange of personnel under this Agreement:

- Whenever an exchange of personnel is contemplated, the Parties shall consult to ensure that the candidates are appropriately qualified to undertake the proposed activity, and to provide the required administrative and logistical support.
- Exchange of personnel under individual projects shall be based on research requirements and approvals, provided during clearance of the project. No further clearances are envisaged for the exchange of such personnel.
- When the long term exchange of personnel is required outside the scope of individual projects, the Parties shall ensure that appropriate clearances are obtained from all responsible Indian and U.S. authorities. The Parties shall establish a formal agreement that documents the duration of the exchange, roles and responsibilities, and any other expectations regarding the performance and support of the personnel.

- Subject to the availability of funds, designated ICER funding or funding provided by the Parties, shall be used to support salaries, insurance, transportation, housing, and all other expenses required to sustain the exchange of personnel.
- All staff and contractors of each Party shall conform to the work rules and safety regulations that are in effect at the hosting facility.

#### Article 6. Laws and Regulations

The Parties shall undertake all activities pursuant to this Agreement in accordance with the established laws, regulations, policies and guidelines of the United States of America and the Republic of India, subject to the availability of personnel, resources, and appropriated funds.

#### Article 7. Protection of Human and Animal Subjects

Both Governments acknowledge the importance of the protection of human and animal subjects in any research, public-health, or medical program. In recognition of this, both Parties agree to follow the laws and regulations for the protection of human and animal subjects adopted by the Republic of India and the United States of America.

#### **Article 8. Intellectual Property and Publications**

- 1. The Parties recognize that the work carried out under this Agreement could produce patentable results, and lead to the publication of scientific findings. The provisions of the S&T Agreement shall govern the allocation of such intellectual property, copyright, and patent rights, except as otherwise specifically agreed by the Parties or their designees pursuant to Section II.A. of the Intellectual Property Annex of the S&T Agreement.
- 2. The Parties shall encourage scientists of both Parties to publish their findings, both jointly and as individuals. In any publication specifically related to work undertaken in areas covered by this Agreement, the Parties shall make an appropriate reference to the ICER program. The Parties shall make scientific and technological information derived from collaborative activities under this Program available to the scientific community, in accordance with the normal procedures of the participating entities. Investigators shall endeavor to conduct their research in a fully transparent manner with their collaborating partners, and disclose all related collaborations that might pose a conflict with research supported under this collaboration.

#### Article 9. General Provisions

1. The U.S. Government and the Government of the Republic of India may provide funding support for activities under this Agreement, depending on the availability of resources. The Parties may seek additional funding and active participation from governmental, non-governmental, private sector, foundation, and other sources, as necessary and consistent with usual and customary practice, to support individual

projects. The Parties may expend funds based on the individual, approved budgets of jointly approved, collaborative research projects and related activities.

- 2. Both Parties recognize work under this Agreement can involve numerous exchanges of administrative and scientific personnel throughout the year. Both Parties agree to facilitate scientific collaboration, using their best efforts to ensure the rapid completion of necessary clearances (including exit permission by the sending country and visa issuance by the receiving country) on a priority basis, subject to each country's respective laws and regulations.
- 3. This Agreement and any activities hereunder shall be subject to, and governed by, the S&T Agreement.
- 4. Each Party hereby agrees that all materials provided by the other Party shall not be distributed to any another organization/individual without the written authorization of the providing Party, except as required by law. Any transfer of biological materials under this program shall be executed in full accordance with each Party's rules, regulations, procedures, and safety precautions.

#### Article 10. Periodic Review Process

The activities of the ICER program shall be reviewed at annual conference calls or joint meetings, attended by representatives of the Parties and the collaborating organizations, as necessary. Reports based on these meetings shall be submitted to ICMR and HHS/NIH/NIAID. Areas for periodic review may include:

- Scientific progress
- Capacity building activities
- Annual budgets
- Exchange of personnel

#### Article 11. Duration, Amendment and Termination

- 1. This Agreement shall enter into force upon signature and shall remain in force for five years. It may be amended, extended, or terminated by mutual written agreement of the Parties.
- 2. The termination of this Agreement shall not affect the validity or duration of any arrangements entered into pursuant to the Agreement prior to its termination.

In witness whereof the undersigned, being duly authorized by their respective Governments, have signed this Agreement.

Signed on the 20th day of May, 2008 in Geneva, in duplicate, in the English language.

Department of Health and Human Services United States of America

Minister

Ministry of Health and Family Welfare Republic of India